APR 1 4 2003

K030603

Pac-Dent International (Suzhou), Inc.

510(k) Summary of Safety and Effectiveness

Submitter:
Pac-Dent International (Suzhou), Inc.
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Jiangsu Province, P. R. China
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Contact Person: Xu Wang
Phone: 909-839-0888
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Date Summary Prepared: Feb.2003

Device Name:
Trade Name: ProAngle™ disposable prophy angle
Common Name: Disposable prophy angle
Classification Name: Handpiece, contra and right angle attachment
Classification: Class I

Devices for Which Substantial Equivalence is Claimed:
Allpro,Inc., Disposable prophy angle

Device Description:
ProAngle™ disposable prophy angle is a device used for polishing and cleaning the surface of teeth. It consists of a pair of gears, a turning spindle and a drive spindle which can connect the low speed handpiece. The turning spindle has a prophylaxis cup on it for polishing or cleaning teeth.

Intended Use of the Device:
The intended use of the ProAngle™ disposable prophy angle is for polishing and cleaning teeth.

Substantial Equivalence:
ProAngle™ disposable prophy angle is substantially equivalent to other legally marketed devices in the United States. ProAngle™ disposable

prophy angles function in a same manner and have the same use as the disposable prophy angle designed by AllPro, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2003

Mr. Xu Wang
General Manager
Pac-Dent International (Suzhou) Limited
125 Binhe Road, New District of Suzhou City,
Jiangsu Province, P.R.
CHINA

Re: K030603
Trade/Device Name: ProAngle™ Disposable Prophy Angle
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: February 18, 2003
Received: February 25, 2003

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801),' please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use statement

Applicant: Pac-Dent International (Suzhou), Ltd.

510(k) Number K030603

Device Name: ProAngle™ disposable prophy angle

Indications For Use:

ProAngle™ disposable prophy angle is a device intended to polish and clean the surface of teeth. It should be attached to a low speed handpiece for operation.

Kevin Mackey S. M. S. M.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030603